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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,101	05/26/2006	Brian Smith	68.US2.PCT	2470
27737 7590 02/04/2009 ARENA PHARMACEUTICALS, INC. 6166 NANCY RIDGE DRIVE SAN DIEGO, CA 92121				
EXAMINER				
LEESER, ERICH A				
ART UNIT		PAPER NUMBER		
1624				
MAIL DATE		DELIVERY MODE		
02/04/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/561,101

**Applicant(s)**

SMITH ET AL.

**Examiner**

Erich A. Leeser

**Art Unit**

1624

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,9,11,12,17,19-37,39,45,46,48,49,51,52,54,59 and 79-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,9,11,12,17,19-37,39,45,46,48,49,51,52,54,59 and 79-83 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-846)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This action is in response to Applicant's submission dated December 9, 2008. Claims 1-3, 9, 11-12, 17, 19-37, 39, 45-46, 48-49, 51-52, 54, 59, and 79-83 are currently pending and under examination.

#### ***Claim Rejections – 35 U.S.C. § 112***

Examiner previously rejected claims 1-3, 9, 11-12, 17, 19-37, 39, 45-46, 48-49, 51-52, 54, 59 and 79-80 under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for making solvates of the claimed invention.

Applicant argues that, "the passages of Vippagunta relied upon in the Office action, which focus on the lack of predictability of the *structure* of solvates, have little relevance to the issue [of] enablement of the claims at issue here because the claims do not require solvates of a particular structure." By arguing the issue of enablement, is Applicant admitting that the invention is indefinite, thereby running afoul of the second paragraph of section 112? In addition, Applicant argues that: "The Office continues to attempt to base its enablement rejection solely on the alleged unpredictability of solvate formation and the fact that no specific examples of solvates have been described in the specification." Is Applicant concluding that a written description rejection is in order in this case? Addressing this argument in the context of Examiner's enablement rejection, Examiner entirely disagrees as set forth in the *Wands* factors, not just the unpredictability of solvate formation in this case. Going thru the individual *Wands* factors, Applicant makes the profound statement, "predicting whether a given solvate is unpredictable".

Applicant also argues by citing Vippagunta that, "[i]t has been estimated that approximately one-third of the pharmaceutically active substances are capable of forming crystalline hydrates" and concludes that "it does not seem to applicants that Vippagunta supports the Examiner's contention that it would be particularly unpredictable whether solvates of compounds of the invention could be formed." If a financial planner proposed a business venture claiming a 33% chance of a return on investment, no reasonably prudent investor would risk their capital on such a venture. Similarly, the Office has every right and does demand that Applicant sufficiently make a showing of enablement, which has not been done in this case regarding solvates.

In addition, Applicant lists nine patents that allowed solvates and hydrates and inquires what is the difference between these cases and the instant case? Apparently, the examiner in each of these other cases felt comfortable that the relevant disclosure adequately taught how to make and/or use the solvates of the patent application at issue. That clearly is not the case here.

The scope of "solvate" is not adequately enabled or defined. Applicants provide no guidance as how the compounds are made more active *in vivo*. Solvates cannot be predicted and there fore are not capable of being properly claimed if the Applicant cannot properly enable a particular solvate.

Because Examiner finds Applicant's argument unpersuasive, this rejection is maintained with regards to claims 1-3, 9, 11-12, 17, 19-37, 39, 45-46, 48-49, 51-52, 54, 59 and 79-83.

Examiner previously rejected claims 33-37, 39, 45-46, 48, -49, 51-52, 54 and 80 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement because the specification does not enable the instant compounds to modulate or treat a 5HT<sub>2C</sub> receptor associated disorder, treat disorders of the central nervous system, treat damage to the CNS; treat cardiovascular disorders; treat GI disorders; treat diabetes insipidus or sleep apnea; decrease food intake, control weight gain or induce satiety of an individual comprising administering a therapeutically-effective amount of a compound of Formula (I) or enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

Examiner withdraws the rejection with regards to claims 33-34 based on Applicant's arguments.

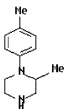
Applicant argues that the: "Office appears now to have dropped its arguments suggesting that Cryan, et al., Hum. Psychopharmacol. Clin. Exp., 2000, 15, 113-135 ("Cryan 1"), supports the rejection by showing "the speculative nature of the role of 5-HT receptors with the treatment of depression" in view of applicants' showing that another paper by Cryan indicated that "the results strongly implicate a role for 5-HT<sub>2C</sub> receptors in the behavioral effects of antidepressant drugs". Examiner would like to clarify that he in no way made any representations to Applicant to indicate any desire to drop his previous arguments.

As such, Examiner maintains this rejection with regards to 35-37, 39, 45-46, 48-49, 51-52, 54 and 80-83.

***Claim Rejections 35 U.S.C. § 103***

Examiner previously rejected claims 1-2, 11-12, 17, 19-26, 32 and 79 under 35 U.S.C. § 103(a) as being unpatentable over Allen, et al., U.S. Patent No. 3,751,417.

Applicant argues that the proviso of claim 1 excludes the compound:  
2-methyl-1-(4-methylphenyl)-piperazine with the following structure.



Upon further reconsideration, Examiner agrees. As such, Examiner withdraws this rejection with regards to claims 1-2, 11-12, 17, 19-26, and 79.

Examiner previously rejected claims 1, 3, 11, 12, 17, 19-25 and 79 under 35 U.S.C. § 103(a) as being unpatentable over Kametani, et al., *Studies on the Syntheses of Heterocyclic Compounds. CDLX. Benzyne Reaction. XIII. Benzyne Reaction of Halogenobenzenes with N-Alkylmorpholines*, J. Org. Chem., Vol. 37, No. 9, 1450-1453 (1972).

Based on Applicant's argument of record, Examiner withdraws this rejection of claims 1, 3, 11, 12, 17, 19-25 and 79.

***Claim Rejections - 35 USC § 102***

Examiner previously rejected claims 1-2, 11-12, 17, 19-26, 32 and 79 under 35 U.S.C. § 102(b) as being unpatentable over Allen, et al., U.S. Patent No. 3,751,417.

Because 2-methyl-1-(4-methylphenyl)-piperazine is included in the proviso in claim 1, but under the name 2-Methyl-1-p-tolyl-piperazine, Examiner withdraws this rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Erich A. Leeser whose telephone number is 571-272-9932. The Examiner can normally be reached Monday through Friday from 8:30 to 6:00 EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. James O. Wilson can be reached at 571-272-0661. The fax number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) toll-free at 866-217-9197. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Erich A. Leeser/

/James O. Wilson/

**Supervisory Patent Examiner, Art Unit 1624**

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